

Regarding this Claim Objection on page 2 of the Detailed Action, please consider new claims 4 through 24. Applicant believes new claims 4-24 are drafted with correct antecedent basis and therefore correct the aforesaid informalities. The new claims define the invention in both methods form and apparatus form with a correct format and applicant believes the aforesaid objection on the basis of informalities is properly overcome.

1) It is noted: claims 1-3 are rejected under USC 102(b) as being anticipated by Rochat (US 5,269,924A). The Examiner recites "Regarding Claim 1, Rochat teaches an apparatus for reducing supplies and waste comprising"(Detailed Action page 2 last line). The Examiner has erred in making said statement. "An apparatus for reducing supplies and waste" is found in the instant case as the preamble of Claim 1 as originally filed not in the Rochat disclosure.

1a) The Rochat subject matter discloses an apparatus for the sterile filtration of blood(column 1 line 7,column 1 line 13, column 1 line 44, column 1 lines 57-60, column 2 lines 40-50, column 2 lines 53-55, column 2 line 67, abstract first line, column 3 lines 40-45, column 3 lines 59-63, column 4 lines 13-15, column 4 lines 17-20, column 4 lines 44- 50, column 4 lines 65-67) and not an apparatus for reducing supplies and waste.

2) It is noted: The Examiner recites "Regarding claim 2, "Rochat teaches an apparatus for disposing waste material in a converted container". (Detailed Action page 4 last line). The Examiner has erred in making this statement. "An Apparatus For Disposing Waste Material In A converted Container Comprising" is found in the instant case as the preamble of claim 2 as originally filed and not in the Rochat disclosure.

2a) The Rochat subject matter discloses an apparatus for the sterile filtration of blood(column 1 line 7,column 1 line 13,-column 1 line 44, column 1 lines 57-60, column 2 lines 40-50, column 2 lines 53-55, column 2 line 67, abstract first line, column 3 lines 40-45, column 3 lines 59-63, column 4 lines 13-15, column 4 lines 17-20, column 4 lines 44-50, column 4 lines 65-67) and not an apparatus for disposing waste material in a converted container.

3) It is note: The Examiner recites "Regarding Claim 3, Rochat teaches an apparatus for converting supplies and reducing waste comprising". (Detailed Action line 12 & 13 middle of page 5). "An apparatus for reducing supplies and converting waste" is found in the instant cast as the preamble of claim 3 and not in the Rochat disclosure.

3a) The Rochat subject matter discloses an apparatus for the sterile filtration of blood(column 1 line 7,column 1 line 13,-column 1 line 44, column 1 lines 57-60, column 2 lines 40-50, column 2 lines 53-55, column 2 line 67, abstract first line, column 3 lines 40-45, column 3 lines 59-63, column 4 lines 13-15, column 4 lines 17-20, column 4 lines 44- 50, column 4 lines 65-67) and not an apparatus for converting supplies and reducing waste.

Based on the aforementioned remarks in Applicants comments 1, 2, & 3 above, and the factual evidence established as Applicants remarks in 1a, 2a & 3a above, the Examiner has erred by using the Preambles of the 3 claims in the instant case as a blueprint and incorrectly defines the subject matter of the Rochat disclosure for arguing the substance of the Rochat teachings against the instant case in hindsight, improperly. *In Re Warner*, 379, F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967) cert. denied, 389 U.S. 1057

(1968). *Gain Processing Corp. v. American Maize-Products, Co.* 840 F.2d 902, 907, 5 USPQ2d 1788, 1792(Fed. Cir. 1988).

Beginning at the top of page 3 of examiners detailed action, the Examiners comparison of the instant case with the Rochat case is made in error based on the following facts in evidence.

Regarding comment a), page 3:

- 1) the bag 10, pipe 15, and pipe 16, are not interposed between a vacuum source and a waste material site. It is not conceivable that blood for filtration and re-infusion would be garnered from a waste site rather from a site of retrievable blood. The Examiners comment defines a reverse scenario which would not be carried out, which would certainly do harm as it defines a reverse process of taking waste and re-infusing it into a patient-no one would do it.
- 2) The draw path of the instant case finds its way through two lid apertures (15 & 18), the Rochat case does not disclose separate paths passing through cover 2.

Regarding comment d)

- 1) the throat aperture plug(s) 7 of the instant case(Fig 12, 14, 15, 17, 18a, 19, 21, 22, 23, in combination with figures 25-29, and figures 32-37,) are each patentably distinct from the plug 21 disclosed in Rochat. The plug 21 of Rochat is not a separate element.(column 3 line 11-15) but a pre-welded assembly comprising plug 21, pipe 15, pipe 16 and bag 10.
- 2) The plug 21 is disclosed to fit into cover 2 of the Rochat device. The throat aperture plug of the instant case is a separate element, separate from the other elements/components of the draw path, IE the tubing, lid etc of the instant case are readily connectable and disconnectable between the throat aperture plug of the instant case and the container of the instant case.
- 3) The throat aperture plug 7 connects with the throat of a container 4 of the instant case. A container neck 4ac connects with a lid 1 in the instant case.
- 4) Rochat does not teach the container 4 lid 1 connection structure of the instant case. There is no separate container in Rochat. The Rochat container 10 does not contact cover 2. The Rochat container does not contact plug 21. The Rochat container contacts pipe 15 and pipe 16 in a pre-affixed manner and pipe 15 and pipe 16 are pre-welded to plug 21. Each of plug 21, pipe 15, pipe 16 and container 10 of Rochat are pre-joined at manufacturing making the disassembly of such impossible, further patentably distinguishing the instant case from the Rochat case based on a structural argument basis.
- 5) Further patentably distinguishing the Rochat disclosure from the instant case is the Rochat requirement that the flexible filtration bag 10 be rolled up and inserted through circular joint 22. (Column 3 lines 16 through 25) This requirement defines the necessity in an absolute sense, that container 10 can only be filled with blood while inside canister 1. This requirement present problems in that the instant case allows a container 4 while full of waste material to be removed separately from a lid/cover from within a canister body 3. Further patentably distinguishing the instant case from the Rochat case is the fact that because plug 21, pipe 15, pipe 16 and bag 10 are inseparably pre joined at manufacturing, it is impossible to fill the bag 10 of the Rochat disclosure and remove the filled bag from cover 2. This proves that the Rochat disclosure never intended for the Rochat disclosure to embody the structure so as to allow a container to be filled with material and then allow separate removal of the material in the container. There is no

structure in the Rochat disclose allowing separation of container 10 from plug 21, pipes 15 and 16. Because it is required to roll flexible blood filtration container 10 along its axis in order to allow placement through cover 2 and into canister 1 prior to use, the same bag rolling requirement exists as required to remove container 10 from cover 2 thereby making it literally impossible to separate container 10 from lid 2 while container 10 is full, requiring the egressing of filtered blood in order to separate the disposable filtration bag, hence evidence that the operating principles of the Rochat reference and the instant case are patentably distinct. Rochat teaches distinctly away from the instant case whereby the instant case allows separation of a full container 4, from a lid 1 while full which is evidence in fact that the art of sterile filtration of blood is non-analogous to the supply chain methods and apparatus of the instant case. The embodiments of the applied Rochat reference, given that said reference is solely directed at filtration of "sterile" blood would never be suitable for such purpose with a subassembly bag 10, pipe 15, pipe 16, and plug 21 that could be separated component by component because the contents are meant to be, inter alia, maintained in a sterile condition, which is why, according to applicant said components are pre-welded at manufacturing. "A reference may be said to teach away when a person of ordinary skill, upon examining the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant". *In Re Gurley*, 27 F.3d 551, 553 31 USPQ 1130, 1131 (Fed. Cir. 1994). The applicant did not follow the path of Rochat because the Rochat structure would render the applicants invention inoperable, and the Rochat reference would never follow the path of the instant case whereas a disconnectable assembly as disclosed by the instant case, and as described herein would render un-sterile(inoperable for its intended purpose of providing filtered sterile blood) the blood products desired to be collected in the Rochat invention.

Further patentably distinguishing the instant case from the Rochat case on the merits of distinct structural limitations, the Rochat case teaches the following claim limitations which are not met when compared to the instant case for carrying out the intended principles of operation of the Rochat case, and when comparing the structure and operational principles of the instant case. "It is axiomatic that anticipation of a claim under 102 can be found only if the prior art reference disclose every element of the claim". *In Re King* 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986) and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458, 221 USPQ 481 485 (Fed. Cir. 1984).

Furthermore the Examiner has erred in not comparing these distinguishing limitation's while examining these two distinct cases "as a whole" and has not compared the heart of these two cases by ignoring these limitations in the detailed office action. *Para-Ordinance Mfg. v. SGS Importers Int'l, Inc.* 73 F.3rd 1085, 1087, 37 USPQ 2d 1237, 1239(Fed. Cir.) cert. denied, citing *W.L. Gore & Assoc., Inc. v. Gorlock, Inc.* 721 F2d 1540, 1548 220 USPQ 303 (Fed. Cir.) cert. denied, 469 US 851 (1984).

a) From Rochat claim 1(Column 4 lines 17-37), 1)a blood collecting and filtration apparatus, 2)adjustable device, 3)reduced pressure line, 4)transverse opening, 5)filtration bag, 6)service position inside enclosure, 7)two superimposed walls, 8)filtration

netting, 9)two walls, 10)peripheral edges, 11)two internal rooms separated by filtration netting, 12)first room connected to inlet pipe, 13)second room connected to outlet pipe, 14)wall-horizontal opening, 15)hydro-phobic air-permeable liquid tight, 16)plug closes transverse opening of said cover. These 16 distinct elements/limitation, inter alia, are essential to the principles of operation of the Rochat reference, are structurally distinct when compared to the instant case, and do not meet and are not found in the instant case and do not read on the claims of the instant case.

b) From Rochat claim 2(lines 39-44), 1)tightness joint plug and cover, 2)adjustable device for connection to a vacuum system, 3)member for controlling pressure, 4)manometer. These additional three distinct elements/limitations, inter alia, are essential to the principles of operations of the Rochat reference, are structurally distinct when compared to the instant case, and do not meet and are not found in the instant case and do not read on the claims of the instant case.

c) From Rochat claim 3(lines 44-64), 1)filtration bag, 2)adjustable device, 3)reduced pressure line, 4)traversing opening, 5)disposable filtration bag, 6)two superimposed walls, 7)filtration netting, 8)fixed between 2 walls, 9)by welding, 10)2 internal rooms, 11)two internal rooms within a disposable filtration bag separated by netting, 12)first room connected to an inlet pipe, 13)a second room connected to an outlet pipe, 14)second room wall has a rectangular horizontal opening in an upper portion, 15)rectangular opening closed by a band of air permeable and liquid tight hydrophobic material, 16)inlet and outlet pipes passing in a tight manner through a plug. These additional distinct 16 elements/limitations, inter alia, are essential to the principles of operations of the Rochat reference, are structurally distinct when compared to the instant case, and do not meet and are not found in the instant case, and do not read on the claims of the instant case as originally filed.

d) From Rochat claim 4(column 4 lines 65-67), whereby said hydrophobic band is provided at least on one side of movable folds of plastic materials.

From a legal perspective, the forgoing facts presented in remarks a, b, c & d above provide proof in evidence that the originally filed claims 1-3 of the instant case do not read on the structural elements/limitations in the claims of the applied Rochat reference, and similarly the claims of the applied Rochat reference do not read on the structural elements/limitations in the claims of the instant case as originally filed. For a prior art reference to anticipate in terms of 35 USC 102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 USPQ 1315, 1317 (Fed. Cir. 1988). Applicant is at a loss for understanding the Examiners application of Rochat as a 102 reference in this case.

Anticipation is established only when a single prior art reference discloses expressly or under the principles of inherency, each and every element of a claimed invention. *RCA Corp. v. Applied Digital Data., Sys., Inc.* 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir) 1984). In other words, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Found. V. Genentech Inc.* 927 F.2d 1565, 18 USPQ 2d 1001, 1010 (Fed. Cir) 1991.

Applicant contends the Examiner erred in applying the Rochat reference, using the instant case as a blueprint for which to write aforesaid office action. See supra.

Applicant presents new methods claims and new apparatus claims in this office action reply for entry into the formal record and for the Examiners consideration in this case, along with the arguments herein presented. Additional apparatus claims, invoking Section 112-6 are included to further broadly claim the subject matter of this instant case which applicant has not found in the prior art of record.

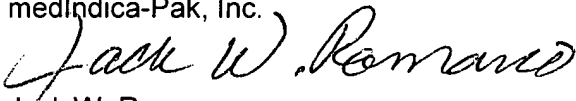
In view of the considerations of the foregoing, it is respectfully submitted that the 102(b) rejections, and the product by process rejections have been successfully overcome by successfully defining factually evidenced based patentable distinctions between the applied Rochat reference and the instant case. Applicant believe the newly submitted claims 4-24 fully address each issue presented by the 03/04/2005 office action and overcome said objections, rejections, as well as the applied Rochat reference. Applicant believes the new claims overcome the prior art of record and are in condition for allowance and respectfully request the examiner move this case to issuance.

Applicant believes the new claims define the instant case in terms of methods and apparatus to an extent to which the applicant is legally entitled to patent protection.

Should the examiner consider necessary or desirable any formal changes anywhere in the specification, claims and/or drawings, then it is respectfully asked that such changes be made by Examiners amendment, if the Examiner feels this would facilitate passage of the case to issuance. Alternatively should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, the examiner is invited to telephone the undersigned.

Respectfully submitted,

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